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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,175

06/26/2003

Peter David White

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EXAMINER

ANDERSON, JAMES D

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

10/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/607,175

Applicant(s)

WHITE ET AL.

Examiner

James D. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18, 20 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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CLAIMS 10-18 and 20-29 ARE PRESENTED FOR EXAMINATION

Applicants' amendment filed 8/10/2007 has been received and entered into the application. Accordingly, claims 10, 13-14, 20, 21, and 27-29 have been amended and claim 19 has been cancelled.

Claims 21-26 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/22/2006.

Applicants' arguments, filed 8/10/2007 have been fully considered and are persuasive to overcome the rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Regrettably, upon further consideration the following rejections are newly applied. They constitute the complete set presently being applied to the instant application.

The indication of allowable subject matter (claims 27-29) in the previous Office Action is hereby *withdrawn* so that the following rejections may be considered.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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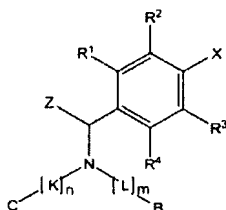
Claims 10-18, 20, and 27-29 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for making a sub-genus of the claimed compounds, does not reasonably provide enablement for making the full scope of compounds encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This is a Scope of Enablement rejection.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The breadth of the claims;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The quantity of experimentation necessary;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The breadth of the claims: Claim 10 and claims dependent therefrom recite building blocks according to the formula:



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wherein the substituents therein are as defined in the claims. Such substituents include highly reactive groups such as NH_2 , CHO , NHNH_2 , COOH , and OH . The K and L substituents encompass any linear or branched, substituted or unsubstituted alkyl chain “with at least two C-atoms” whereby one or more non-neighboring C-atoms are optionally substituted by O, NH, N-(C_1 - C_6)Alkyl, N-(C_5 - C_{15})Aryl, S, a carbonyl group, ester group, or an amide group, and/or neighboring C-atoms are optionally connected by a double or triple bond. The X substituent is –D- R^5 -E- wherein R^5 is C_1 - C_{10} alkyl. The Z substituent can be H, C_1 - C_8 -alkyl, C_5 - C_{20} aryl, or C_5 - C_{20} heteroaryl. R^1 , R^2 , R^3 , and R^4 range from hydrogen to C_5 - C_{18} aryl or heteroaryl. The B substituent can be any “amino protecting group” or simply an amino group. The C substituent can be “one or more labels” or functionality selected from NH_2 , OH , NHNH_2 , NHOH , CHO , “or a protected form thereof”. The claims thus encompass millions of possible compounds having chemically and structurally distinct substituents. Thus, the scope of the above claims is extremely broad.

The amount of direction or guidance presented: Although the specification provides a method of making a single building block of the invention (building block 1 in Figure 4), it does not provide working examples sufficient to guide the skilled chemist to make compounds with any reasonable correlation to the scope of the claims. There is no guidance on what types of protecting groups might be required to avoid polymerization, cyclization, cross-reactivity, etc. when making the claimed compounds. It is not seen that the skilled artisan could simply substitute any starting materials into the one method described in the specification to make a number of compounds that bears any reasonable correlation to the scope of the claims. Thus, the

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specification fails to provide sufficient enablement for making the claimed compounds, other than compound 1 as shown in Figure 4 and compounds similar to this compound having different labels attached thereto.

The state of the prior art: Although the level of skill in the art is high, it is not a simple matter for the skilled chemist to see a compound structure and readily synthesize the compound. The process for selecting particular protecting group strategies, solvents, reaction times, purification techniques, etc. is not standard for all compounds. For the claimed compounds, there is no reference teaching a general synthetic strategy that may be employed. Thus, the state of the prior art does not support the broad scopes of the above claims.

The relative skill of those in the art: Even with advanced training, the skilled chemist would have to engage in extensive research to determine suitable starting materials and synthetic strategies for each compound from the large Markush group of Formula 1. Not only has one to determine appropriate starting materials, but also protecting groups to avoid possible cross-reactivity and unwanted reactions, and suitable solvent systems and purification techniques for each compound and the intermediates in the synthetic pathway thereto. Given the plethora of compounds encompassed by the claims, such a task would require a tremendous amount of effort, time and resource.

The predictability or unpredictability of the art & The quantity of experimentation

necessary: The process of making any given compound as recited in the claims requires at the

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very least three steps: (1) a retro synthetic analysis to determine appropriate starting materials and synthetic strategy; (2) synthesis of the appropriate starting materials if they are not commercially available; and (3) a series of synthetic steps, including protecting group addition and removal if appropriate, purification of synthesized intermediates, and coupling of intermediates in a series of reactions to produce the desired compound. On the pathway to any given compound, there is inherent unpredictability in each of the above steps. For example, one synthetic pathway may not be feasible because one or more starting materials cannot be readily purchased or synthesized. Or, a particular reaction step may not work because the reaction conditions are not appropriate (*e.g.*, wrong solvent, wrong temperature, wrong reaction time, wrong protecting groups). Thus, the process of making any given compound encompassed by the claims is highly unpredictable due to many unknown factors inherent in chemical synthesis.

Accordingly, the claims fail to comply with 35 U.S.C. § 112, 1st Paragraph because the skilled artisan would have to carry out undue, painstaking research to make compounds of the invention other than those compounds for which Applicants have provided explicit guidance and conditions for their synthesis.

Claims 10, 13-18, and 20 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

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Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plain for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.I "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicant has failed to provide any written description for the limitation "peptides" as recited in claim 10. It is well known in the art that a peptide is a sequence of two or more amino acids. However, Applicants have not described any particular peptide sequences contemplated to be used in the present invention. While there are only 20 naturally occurring amino acids, there are billions of possible peptide sequences. As such, recitation of "peptides" fails to provide

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adequate written description for exactly what peptide sequences are contemplated for use in the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



James D. Anderson
Patent Examiner
AU 1614

October 25, 2007


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER